

materials, Nuclear power plants and reactors, Penalties, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendment to 10 CFR part 2.

PART 2—RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS AND ISSUANCE OF ORDERS

1. The authority citation for part 2 continues to read as follows:

Authority: Secs. 161, 181, 68 Stat. 948, 953, as amended (42 U.S.C. 2201, 2231); sec. 191, as amended, Pub. L. 87-615, 76 Stat. 409 (42 U.S.C. 2241); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); 5 U.S.C. 552.

Section 2.101 also issued under secs. 53, 62, 63, 81, 103, 104, 105, 68 Stat. 930, 932, 933, 935, 936, 937, 938, as amended (42 U.S.C. 2073, 2092, 2093, 2111, 2133, 2134, 2135); sec. 114(f), Pub. L. 97-425, 96 Stat. 2213, as amended (42 U.S.C. 10134(f)); sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332); sec. 301, 88 Stat. 1248 (42 U.S.C. 5871). Sections 2.102, 2.103, 2.104, 2.105, 2.721 also issued under secs. 102, 103, 104, 105, 183, 189, 68 Stat. 936, 937, 938, 954, 955, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2233, 2239). Section 2.105 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 2.200-2.206 also issued under secs. 161b, i, o, 182, 186, 234, 68 Stat. 948-951, 955, 83 Stat. 444, as amended (42 U.S.C. 2236, 2282); sec. 206, 88 Stat. 1246 (42 U.S.C. 5846). Sections 2.600-2.606 also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853, as amended (42 U.S.C. 4332). Sections 2.700a, 2.719 also issued under 5 U.S.C. 554. Sections 2.754, 2.760, 2.770, 2.780 also issued under 5 U.S.C. 557. Section 2.764 and Table 1A of Appendix C also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 2.790 also issued under sec. 103, 68 Stat. 936, as amended (42 U.S.C. 2133) and 5 U.S.C. 552. Sections 2.800 and 2.808 also issued under 5 U.S.C. 553. Section 2.809 also issued under 5 U.S.C. 553 and sec. 29, Pub. L. 85-256, 71 Stat. 579, as amended (42 U.S.C. 2039). Subpart K also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Subpart L also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239). Appendix A also issued under sec. 6, Pub. L. 91-560, 84 Stat. 1473 (42 U.S.C. 2135). Appendix B also issued under sec. 10, Pub. L. 99-240, 99 Stat. 1842 (42 U.S.C. 2021b et seq.).

2. Section 2.810 is added to read as follows:

§ 2.810 NRC size standards.

The NRC shall use the size standards contained in this section to determine whether a licensee qualifies as a small entity in its regulatory programs.

(a) A small business is a for-profit concern and is a—

(1) Concern that provides a service or a concern not engaged in manufacturing with average gross receipts of \$5 million or less over its last 3 completed fiscal years; or

(2) Manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

(b) A small organization is a not-for-profit organization which is independently owned and operated and has annual gross receipts of \$5 million or less.

(c) A small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000.

(d) A small educational institution is one that is—

(1) Supported by a qualifying small governmental jurisdiction; or

(2) Not state or publicly supported and has 500 or fewer employees.

(e) For the purposes of this section, the NRC shall use the Small Business Administration definition of receipts (13 CFR 121.402(b)(2)). A licensee who is a subsidiary of a large entity does not qualify as a small entity for purposes of this section.

Dated at Rockville, Maryland, this 31st day of March, 1995.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 95-8843 Filed 4-10-95; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 95-AWP-4]

Alteration of Class D Airspace; Williams Air Force Base (AFB), AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: An error was discovered in a rule that was published in the **Federal Register** on March 15, 1995, Airspace Docket No. 95-AWP-4. The correct title description was inadvertently omitted from the rule. The alteration of this Class D airspace should only reflect the renaming of the airport from Williams

AFB, AZ, to Williams Gateway Airport, AZ. This action corrects that error.

EFFECTIVE DATE: 0901 UTC, May 25, 1995.

FOR FURTHER INFORMATION CONTACT:

Scott Speer, System Management Specialist, System Management Branch, AWP-530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 297-0010.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 95-6380, Airspace Docket No. 95-AWP-4, published on March 15, 1995 (60 FR 13900), altered the Class D airspace at Williams AFB, AZ. The correct title description and geographic location of this Class D airspace is Chandler, AZ, which was inadvertently omitted from the rule. The only alteration of this Class D airspace area at Chandler, AZ, is the renaming of the airport to Williams Gateway Airport, AZ, due to the closure of Williams AFB, AZ. This action corrects that error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the description for the Class D airspace at Williams Air Force Base (AFB), AZ, as published in the **Federal Register** on March 15, 1995 (60 FR 13900) (**Federal Register** Document 95-6380; page 13901, column 1), and the description in FAA Order 7400.9B, which is incorporated by reference in 14 CFR 71.1 are corrected as follows:

§ 71.1 [Corrected]

On page 13901, in column 1, under Paragraph 5000, the first line of the airspace designation is corrected to read as follows:

* * * * *

AWP AZ D Chandler, AZ [Revised]

* * * * *

Issued in Los Angeles, California, on March 27, 1995.

Dennis T. Koehler,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 95-8767 Filed 4-10-95; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY**Customs Service**

19 CFR Parts 7, 11, 12, 18, 19, 24, 54, 101, 102, 111, 114, 123, 128, 132, 134, 141, 145, 146, 148, 151, 152, 177, 181, and 191

[T.D. 95-29]

Technical Amendments to the Customs Regulations

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations by making certain technical corrections to various authority citations to reflect amendments to the Harmonized Tariff Schedule of the United States made by the North American Free Trade Agreement (NAFTA) and the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).

EFFECTIVE DATE: April 11, 1995.

FOR FURTHER INFORMATION CONTACT: Gregory R. Vilders, Attorney, Regulations Branch (202) 482-6930.

SUPPLEMENTARY INFORMATION:**Background**

At present, due to certain amendments to the Harmonized Tariff Schedule of the United States (HTSUS) that resulted in many of the General Notes of the HTSUS being renumbered, many authority citations in the Customs Regulations that reference certain General Note provisions are no longer accurate.

In 1994, when the HTSUS was amended to incorporate changes made by the North American Free Trade Agreement (NAFTA) (see Presidential Proclamation 6641 of December 15, 1993, published in the **Federal Register** on December 20, 1993 (58 FR 66867, 67032)), General Notes 4 through 9 were redesignated as General Notes 13 through 18, respectively, and new General Notes 4 through 12 were added. This addition of nine new General Notes caused the General Note numbering scheme to change. In 1995, when the HTSUS was again amended to incorporate changes necessitated by provisions of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) (see Presidential Proclamation 6763 of December 23, 1994, published in the **Federal Register** on January 4, 1995 (60 FR 1007, 1018)), the General Notes were modified by renumbering General Notes 13 through 18 as General Notes 16 through 21, respectively, and

inserting new General Notes 13 through 15. The addition of three more General Notes again caused the General Note numbering scheme to change.

For example, one of the authorities for many Customs Regulations, as detailed below, is the General Note which provides that the Secretary of the Treasury is authorized to issue rules and regulations governing the admission of articles under the provisions of the tariff schedule. This General Note was initially designated as General Note 8 when the Harmonized Tariff Schedule was adopted in 1989, became General Note 17 in 1994, and, in 1995, is now designated as General Note 20.

Customs also cites as authority for many sections detailed below the General Note which provides that the Secretary of the Treasury is authorized to prescribe methods of ascertainment whenever he finds that such methods are necessary for purposes of any law administered by the Customs Service. This General Note was initially designated as General Note 9 when the Harmonized Tariff Schedule was adopted in 1989, became General Note 18 in 1994, and, in 1995, is now designated as General Note 21.

This document updates and corrects those references in the Customs Regulations to the HTSUS General Notes.

Discussion of Changes**Part 7**

The authority citation for Part 7 references General Note 8 of the HTSUS. Since this General Note is now designated as General Note 20, as discussed above, the reference is revised accordingly.

Part 11

The authority citation for Part 11 references General Note 9 of the HTSUS. Since this General Note is now designated as General Note 21, as discussed above, the reference is revised accordingly.

Part 12

The general authority citation for Part 12 references General Note 17 of the HTSUS. Since this General Note is now designated as General Note 20, the reference is revised accordingly.

Parts 18, 19, and 24

The general authority citation for Parts 18 and 19 reference General Note 8 of the HTSUS, and the general authority citation for Part 24 references General Note 17 of the HTSUS, both provisions in different editions of the HTSUS providing for the regulations authority notes discussed above. For the

reasons given above, these references are revised to read General Note 20. Also, § 24.23(c)(1)(v) references General Note 4 of the HTSUS, which deals with exemptions. Since this General Note is now designated as General Note 16, the reference is revised accordingly.

Parts 54, 101, 102, 111, 114, 123, 128, 132, and 134

The authority citations for Parts 54, 101, 102, 111, 114, 123, 128, 132, and 134 reference General Note 8 of the HTSUS. For the reason given above, these references are revised to reference General Note 20.

Part 141

Section 141.4(a) of Part 141 references General Note 4 of the HTSUS. For the reason given above, this reference is revised to reference General Note 16.

Parts 145, 146, 148, and 151

The authority citations for Parts 145, 146, 148, and 151 reference General Note 8 of the HTSUS. For the reason given above, these references are revised to reference General Note 20. Also in Part 151, the authority citation references General Note 9 of the HTSUS. For the reason given above, this reference is revised to reference General Note 21.

Part 152

The specific authority citation for subpart D of Part 152 and several provisions of § 152.13 reference General Note 5 of the HTSUS, which dealt with the commingling of goods. Since this General Note is now designated as General Note 17, the reference is revised accordingly.

Parts 177, 181, and 191

The general authority citations for Parts 177, 181, and 191 reference General Note 17 of the HTSUS. For the reason given above, these references are revised to reference General Note 20.

Inapplicability of Public Notice and Comment Requirements, Delayed Effective Date Requirements, the Regulatory Flexibility Act, and Executive Order 12866

Inasmuch as these amendments merely correct certain referencing errors in the Customs Regulations, pursuant to 5 U.S.C. 553(a)(2) and (b)(B), good cause exists for dispensing with notice and public procedure thereon as unnecessary. For the same reason, good cause exists for dispensing with the requirement for a delayed effective date, under 5 U.S.C. 553(a)(2) and (d)(3). Since this document is not subject to the notice and public procedure

requirements of 5 U.S.C. 553, it is not subject to provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This amendment does not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

Drafting Information

The principal author of this document was Gregory R. Vilders, Attorney, Office of Regulations and Rulings, Regulations Branch.

Amendments to the Regulations

The authority citations to those parts of chapter 1 of the Customs Regulations (19 CFR chapter 1) listed below are amended as set forth below:

PART 7—CUSTOMS RELATIONS WITH INSULAR POSSESSIONS AND GUANTANAMO BAY NAVAL STATION

1. The authority citation for Part 7 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624; 48 U.S.C. 1406i.

PART 11—PACKING AND STAMPING; MARKING

1. The authority citation for Part 11 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 21, Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

PART 12—SPECIAL CLASSES OF MERCHANDISE

1. The general authority citation for Part 12 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

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PART 18—TRANSPORTATION IN BOND AND MERCHANDISE IN TRANSIT

1. The general authority citation for Part 18 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1551, 1552, 1553, 1624;

* * * * *

PART 19—CUSTOMS WAREHOUSES, CONTAINER STATIONS AND CONTROL OF MERCHANDISE THEREIN

1. The general authority citation for Part 19 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

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PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

1. The general authority citation for Part 24 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58a–58c, 66, 261, 267, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1450, 1624; 31 U.S.C. 9701, unless otherwise noted.

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§ 24.23 [Amended]

2. In § 24.23, the reference in paragraph (c)(1)(v) to "General Note 4" is revised to read "General Note 16".

PART 54—CERTAIN IMPORTATIONS TEMPORARILY FREE OF DUTY

1. The authority citation for Part 54 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Section XV, Note 5, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

PART 101—GENERAL PROVISIONS

1. The authority citation for Part 101 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

PART 102—RULES OF ORIGIN

1. The authority citation for Part 102 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624, and the North American Free Trade Agreement Implementation Act, Pub.L. 103–182, 107 Stat. 2057.

PART 111—CUSTOMS BROKERS

1. The general authority citation for Part 111 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624, 1641;

* * * * *

PART 114—CARNETS

1. The authority citation for Part 114 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

PART 123—CUSTOMS RELATIONS WITH CANADA AND MEXICO

1. The general authority citation for Part 123 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1431, 1433, 1624;

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PART 128—EXPRESS CONSIGNMENTS

1. The authority citation for Part 128 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1321, 1484, 1498, 1551, 1555, 1556, 1565, 1624.

PART 132—QUOTAS

1. The authority citation for Part 132 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

PART 134—COUNTRY OF ORIGIN MARKING

1. The authority citation for Part 134 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1304, 1624.

PART 141—ENTRY OF MERCHANDISE

1. The general authority citation for Part 141 continues to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624;

* * * * *

§ 141.4 [Amended]

2. In § 141.4, the reference in paragraph (a) to "General Note 4" is revised to read "General Note 16".

PART 145—MAIL IMPORTATIONS

1. The general authority citation for Part 145 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

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PART 146—FOREIGN TRADE ZONES

1. The general authority citation for Part 146 is revised to read as follows:

Authority: 19 U.S.C. 66, 81a–81u, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624;

* * * * *

**PART 148—PERSONAL
DECLARATIONS AND EXEMPTIONS**

1. The general authority citation for Part 148 is revised to read as follows:

Authority: 19 U.S.C. 66, 1496, 1498, 1624. The provisions of this part, except for subpart C, are also issued under 19 U.S.C. 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS));

* * * * *

**PART 151—EXAMINATION,
SAMPLING, AND TESTING OF
MERCHANDISE**

1. The general authority citation for Part 151 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Notes 20 and 21, Harmonized Tariff Schedule of the United States (HTSUS)), 1624. Subpart A also issued under 19 U.S.C. 1499. * * *

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**PART 152—CLASSIFICATION AND
APPRAISEMENT OF MERCHANDISE**

1. The general authority citation for Part 152 is unchanged, but the specific authority for subpart D and for §§ 152.13 and 152.24 are revised, to read as follows:

Authority: 19 U.S.C. 66, 1401a, 1500, 1502, 1624;

* * * * *

Subpart D also issued under 19 U.S.C. 1202 (General Note 17, Harmonized Tariff Schedule of the United States (HTSUS));

* * * * *

Sections 152.13 and 152.24 also issued under 19 U.S.C. 1202 (General Note 17, Harmonized Tariff Schedule of the United States (HTSUS)).

§ 152.13 [Amended]

2. In § 152.13, the reference in paragraphs (b)(1), (b)(2), (c) introductory text, (c)(1), (c)(2), (c)(3), and (d) to "General Note 5" is revised to read "General Note 17".

**PART 177—ADMINISTRATIVE
RULINGS**

1. The general authority citation for Part 177 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

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**PART 181—NORTH AMERICAN FREE
TRADE AGREEMENT**

1. The authority citation for Part 181 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624, and the North American Free Trade Agreement

Implementation Act, Pub. L. 103-182, 107 Stat. 2057.

PART 191—DRAWBACK

1. The general authority citation for Part 191 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1313, 1624;

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Dated: April 4, 1995.

Stuart P. Seidel,

*Assistant Commissioner, Office of
Regulations and Rulings.*

[FR Doc. 95-8745 Filed 4-10-95; 8:45 am]

BILLING CODE 4820-02-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 176 and 178**

[Docket No. 93N-0420]

**Indirect Food Additives: Paper and
Paperboard Components; Adjuvants,
Production Aids, and Sanitizers;
Technical Amendment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct an error in nomenclature for a food additive. The amendment adds alkyl mono- and disulfonic acids, sodium salts (produced from *n*-alkanes in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆) as a component of paper and paperboard in contact with food, as an antistatic agent, and as an emulsifier and/or surface active agent. Additionally, because certain sections contain multiple entries for the additive, FDA is amending its food additive regulations so that all uses of the additive will be combined under single entries in those sections of the regulations.

DATES: Effective April 11, 1995; written objections and requests for a hearing by May 11, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew Zajac, Center for Food Safety and Applied Nutrition (HFS-216), Food

and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3095.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 21, 1994 (59 FR 3322), FDA published a proposed rule to correct an error in nomenclature for a food additive regulated in §§ 176.170, 176.180, 178.3130, and 178.3400 (21 CFR 176.170, 176.180, 178.3130, and 178.3400). The agency proposed to add alkyl mono- and disulfonic acids, sodium salts (produced from *n*-alkanes in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆) to those sections and to remove: (1) The listing "*n*-alkylsulfonate (alkyl group is in the range C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" from § 176.170; (2) the listing "petroleum sulfonates" from the list of substances in § 176.180; (3) the listings for "sodium *n*-alkylsulfonate (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" and "sodium sec-alkyl mono- and disulfonates (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" from § 178.3130; and (4) the listings for "*n*-alkylsulfonate (alkyl group is in the range C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" and "sodium sec-alkyl mono- and disulfonates (alkyl group in the range of C₁₀-C₁₈ with not less than 50 percent C₁₄-C₁₆)" from § 178.3400.

FDA received no comments on its proposal. The agency is, therefore, adopting the proposal as a final rule without any changes.

The agency has previously considered the environmental effects of this rule, as announced in the proposed rule (59 FR 3322, January 21, 1994). No new information or comments have been received that would affect the agency's previous determination that this action will not have a significant impact upon the human environment and that neither an environmental assessment nor an environmental impact statement is required.

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined